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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,442	07/18/2003	Tae-Wan Kim	66195/JPW/AJM/JCS	3560

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EXAMINER	
HADDAD, MAHER M	
ART UNIT	**PAPER NUMBER**
1644	

MAIL DATE	DELIVERY MODE
05/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,442	KIM ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/2/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 4/2/07, is acknowledged.

2. Claim 4 is pending and under examination.

3. For clarity reasons, it is suggested that the claim 4 recites a carrier as being the 16 amino acids polypeptide.

4. Applicant's ID, filed 4/2/07, is acknowledged.

5. The following new grounds of rejections are necessitated by the amendment submitted 4/2/07.

6. The amendment filed 04/2/07 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "which has the amino acid sequence RQIKIWFQNRRMKWKK (SEQ ID NO:2), and is manufactured by Qbiogene, Inc. (Irvine, CA).

An incorporation of the 16 amino acid polypeptide added after the filing date of an application is not permitted because no new matter can be added to an application after its filing date. However, this incorporation of the sequence would be permitted if Applicant provides showing that the Penetratin® sequence and SEQ ID NO: 2 are the same at the time the invention was made provided in a declaration format.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The phrases "having a molecular weight of about 14 to 17 kDa" and " an amino acid sequence as set forth in SEQ ID NO:2" claimed in claim 4 represent a departure from the specification and the claims as originally filed.

Applicant's amendment filed 4/2/07 does not points to the specification for support for the newly added limitations as claimed in claim 4. However, the specification does not provide a clear support of for such limitation. The Examiner notes that MW of about 14 to 17 kDa is not in the

specification, but figure 4B depicts a band between the MW marker 14-17. However, the term "about" indicates that the polypeptide can be 12, 13, 14, 15, 16, 17, 18 or 19 kDa. Further, Fig. 4B provides a single band with a specific MW, not a polypeptide with range of MWs. Regarding "SEQ ID NO: 2", see the above comments. The instant claims now recite limitations, which were not clearly disclosed in the specification and recited in the claims as originally filed.

9. In view of the amendment filed on 4/2/07, only the following rejections are remained.

10. Claim 4 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the same reasons set forth in the previous Office Action mailed 9/27/06.

Applicant's arguments, filed 4/2/07, have been fully considered, but have not been found convincing.

Regarding the issue that the specification fails to disclose any particular function or biological significance for the CD44-ICD polypeptide. Applicants submits that they note that the CD44-ICD polypeptide corresponds to the soluble domain of CD44 having a molecular weight of about 14 to 17 kDa recited in amended claim 4.

However, Applicant fails to state the particular function or biological significance for the claimed CD44-ICD polypeptide. Applicant fails to address the issue at hand. The issue was not the structure of the claimed CD44-ICD but the function of the polypeptide.

Regarding, the statement "that it is not the CD44ICD that is associated with the observed growth inhibition induced by HA, but rather the soluble CD44 fragment". The examiner thanks applicant for pointing out that this statement is wrong. The statement should be that it is not the CD44ICD that is associated with the observed growth inhibition induced by HA, rather than soluble CD44 fragment. This is supported by Applicant's specification as indicated by the remarks.

Applicant submits that γ-secretase-mediated cleavage of CD44, i.e., production of CD44-ICD, which is associated with the observed growth inhibition induced by HA, is actually attributable to CD44-ICD.

However, what is being claimed is the CD44-ICD polypeptide. The polypeptide has not show to inhibit induced growth by HA.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 4 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Okamoto et al (1999) or Okamoto et al (2001) each in view of US. Pat. No. 5,968,824 for the same reasons set forth in the previous Office Action mailed 9/27/06.

Applicant's arguments, filed 4/2/07, have been fully considered, but have not been found convincing.

Applicants direct the Examiner's attention to the printout of the Penetratin™ 1 product from the Qbiogene website (Exhibit B). Specifically on page 2 of the printout, various applications for Penetratin TM 1 are listed. Nowhere is there a teaching or suggestion to use Penetratin for the internalization of a soluble intracellular domain of a receptor. Accordingly, it would not have been obvious for one skilled in the art to combine the teachings of the references cited by the Examiner to obtain the invention defined by amended claim 4.

However, the rejection was made in view of the 5,968,824 patent, not in view of Qbiogene website. Applicant arguments are without merit.

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 27, 2007

Maher Haddad

Maher Haddad, Ph.D.
Primary Examiner
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